

**AMENDMENTS TO THE CLAIMS**

Please amend the claims as follows.

Claim 1 (withdrawn): A pharmaceutical formulation comprising one or  
5 more excipients and 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\alpha$ -  
dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\beta$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane,  
3 $\beta$ ,16 $\alpha$ -dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\beta$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -  
androstane, 3 $\alpha$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\alpha$ -androstane, 3 $\beta$ ,16 $\beta$ -dihydroxy-17-  
oxo-5 $\alpha$ -androstane, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane, 3 $\alpha$ ,16 $\alpha$ -dihydroxy-  
10 17-oxo-5 $\beta$ -androstane, 3 $\beta$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane, 3 $\beta$ ,16 $\alpha$ -  
dihydroxy-17-oxo-5 $\beta$ -androstane, 3 $\alpha$ ,16 $\beta$ ,17 $\beta$ -trihydroxy-5 $\beta$ -androstane,  
3 $\alpha$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\beta$ -androstane, 3 $\beta$ ,16 $\beta$ -dihydroxy-17-oxo-5 $\beta$ -  
androstane or a 2-oxa, 11-oxa or 19-nor analog of any of these compounds.

15 Claim 2 (withdrawn): The pharmaceutical formulation of claim 1  
wherein the compound is 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-5 $\alpha$ -androstane.

Claim 3 (withdrawn): The pharmaceutical formulation of claim 1  
wherein the compound is 3 $\alpha$ ,16 $\alpha$ -dihydroxy-17-oxo-5 $\alpha$ -androstane.

20 Claim 4 (withdrawn): A pharmaceutical formulation for buccal or  
sublingual administration comprising one or more excipients and a compound  
wherein the compound is 16 $\alpha$ -fluoro-17-oxoandrost-5-ene, 3 $\alpha$ -hydroxy-16 $\alpha$ -  
fluoro-17-oxoandrost-5-ene, 3 $\beta$ -hydroxy-16 $\alpha$ -fluoro-17-oxoandrost-5-ene 7 $\alpha$ -  
25 hydroxy-16 $\alpha$ -fluoro-17-oxoandrost-5-ene, 7 $\beta$ -hydroxy-16 $\alpha$ -fluoro-17-  
oxoandrost-5-ene, 16 $\alpha$ -fluoro-7,17-dioxoandrost-5-ene.

Claim 5 (withdrawn): The pharmaceutical formulation of claim 4  
wherein the compound is micronized.

Claim 6 (withdrawn): The pharmaceutical formulation of claim 4  
wherein the compound is 16 $\alpha$ -fluoro-17-oxoandrost-5-ene.

Claim 7 (withdrawn): A pharmaceutical formulation comprising one or  
5 more excipients and two or more of 3 $\beta$ -hydroxy-16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -  
androstane, 3 $\beta$ -hydroxy-16 $\beta$ -bromo-17-oxo-5 $\alpha$ -androstane and 3 $\beta$ -hydroxy-  
16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -androstane hemihydrate.

Claim 8 (withdrawn): The pharmaceutical formulation of claim 7  
10 wherein the pharmaceutical formulation is for oral, buccal, sublingual or  
aerosol administration.

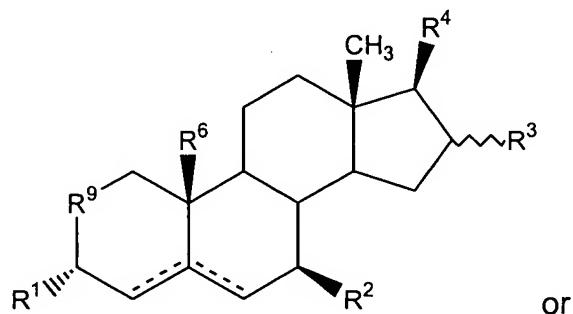
Claim 9 (original): The pharmaceutical formulation of claim 7  
comprising 7 3 $\beta$ -hydroxy-16 $\beta$ -bromo-17-oxo-5 $\alpha$ -androstane and 3 $\beta$ -hydroxy-  
15 16 $\alpha$ -bromo-17-oxo-5 $\alpha$ -androstane hemihydrate.

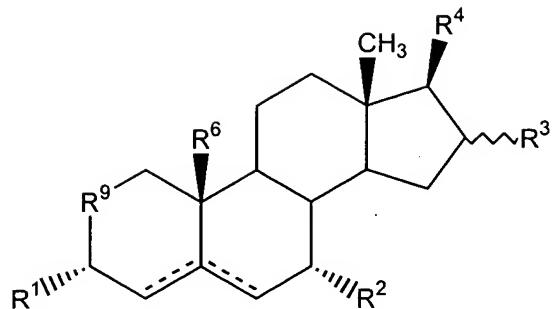
Claim 10 (withdrawn): The pharmaceutical formulation of claim 9  
wherein the pharmaceutical formulation is for oral, buccal, sublingual or  
aerosol administration.

20

Claims 11-31 (canceled)

Claim 32 (new): A method to treat osteoporosis or a bone fracture in a  
subject in need thereof, comprising administering to the subject an effective  
25 amount of a compound having the structure





wherein,

R<sup>1</sup> is -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, -NO<sub>2</sub>, an ester, a thioester, a phosphoester, a phosphothioester, a sulfate ester, an amino acid, a peptide, 5 an ether, a thioether, a carbonate, a carbamate, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

R<sup>2</sup> and R<sup>3</sup> independently are -H, -OR<sup>PR</sup>, =O, -SR<sup>PR</sup>, =S, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, =NOH, -CN, -NO<sub>2</sub>, an amino acid, a peptide, an ether, a thioether, an acyl group, a thioacyl group, a carbonate, a carbamate, a thioacetal, a halogen, a 10 substituted alkyl group, an optionally substituted alkenyl group, an optionally substituted alkynyl group;

R<sup>4</sup> is -OR<sup>PR</sup>, =O, -SR<sup>PR</sup>, =S, -N(R<sup>PR</sup>)<sub>2</sub>, -N<sub>3</sub>, =NOH, -NO<sub>2</sub>, an ester, a thioester, a phosphoester, a phosphothioester, a phosphonoester, a phosphiniester, a sulfate ester, an amino acid, a peptide, an ether, a 15 thioether, an optionally substituted heteraryl moiety, an optionally substituted monosaccharide or an optionally substituted oligosaccharide;

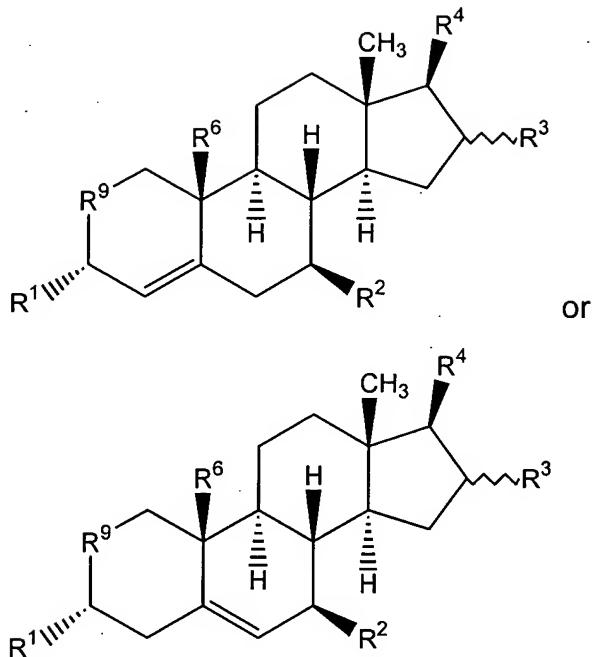
R<sup>6</sup> is -H or optionally substituted alkyl;

R<sup>9</sup> is -CHR<sup>10</sup>-, wherein R<sup>10</sup> is -H, -OH, =O, -SH, halogen, an ester, a thioester, an amino acid, a peptide, an ether, a thioether, optionally 20 substituted alkyl, optionally substituted alkenyl or optionally substituted alkynyl;

R<sup>13</sup> independently is C<sub>1-6</sub> alkyl;

R<sup>PR</sup> independently are -H or a protecting group.

25 Claim 33 (new): The method of claim 32 wherein the subject has osteoporosis and the compound has the structure



Claim 34 (new): The method of claim 33 wherein

5       (1) R<sup>1</sup> and R<sup>4</sup> are -OH, R<sup>2</sup> and R<sup>3</sup> are -H and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (2) R<sup>1</sup> and R<sup>4</sup> are -OH, R<sup>2</sup> is -H, R<sup>3</sup> is -Br and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (3) R<sup>1</sup> and R<sup>4</sup> are -OH, R<sup>2</sup> is -H, R<sup>3</sup> is -F and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (4) R<sup>1</sup>, R<sup>2</sup> and R<sup>4</sup> are -OH, R<sup>3</sup> is -H and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (5) R<sup>1</sup>, R<sup>2</sup> and R<sup>4</sup> are -OH, R<sup>3</sup> is -Br and R<sup>9</sup> is -CH<sub>2</sub>-;  
10       (6) R<sup>1</sup>, R<sup>2</sup> and R<sup>4</sup> are -OH, R<sup>3</sup> is -F and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (7) R<sup>1</sup>, R<sup>3</sup> and R<sup>4</sup> are -OH, R<sup>2</sup> is -H and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (8) R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> are -OH and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (9) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a  
15       thioester, a phosphoester, a monosaccharide, an oligosaccharide, a  
carbonate or a carbamate, R<sup>2</sup> and R<sup>3</sup> are -H and R<sup>9</sup> is -CH<sub>2</sub>-;  
        (10) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a  
thioester, a phosphoester, a monosaccharide, an oligosaccharide, a  
carbonate or a carbamate, R<sup>2</sup> is -H, R<sup>3</sup> is -Br and R<sup>9</sup> is -CH<sub>2</sub>-;  
20       (11) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a  
thioester, a phosphoester, a monosaccharide, an oligosaccharide, a  
carbonate or a carbamate, R<sup>2</sup> is -H, R<sup>3</sup> is -F and R<sup>9</sup> is -CH<sub>2</sub>-;

(12) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R<sup>2</sup> is -H, R<sup>3</sup> is -OH and R<sup>9</sup> is -CH<sub>2</sub>-;

5 (13) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R<sup>2</sup> and R<sup>3</sup> are -OH and R<sup>9</sup> is -CH<sub>2</sub>-;

(14) R<sup>1</sup> and R<sup>4</sup> independently are -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate, R<sup>2</sup> is -OH, R<sup>3</sup> is -H, -F, -Cl or -Br and R<sup>9</sup> is -CH<sub>2</sub>-;

10 (15) R<sup>1</sup> is -H, R<sup>2</sup> is -OH or =O, R<sup>3</sup> is -OH, -F, -Cl or -Br, R<sup>4</sup> is -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R<sup>9</sup> is -CH<sub>2</sub>-;

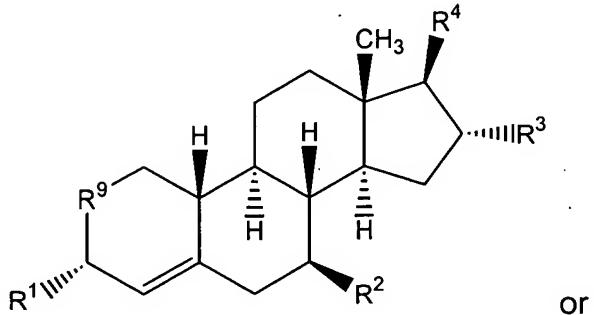
15 (16) R<sup>1</sup> and R<sup>2</sup> are -H, R<sup>3</sup> is -OH or =O, -F, -Cl or -Br, R<sup>4</sup> is -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R<sup>9</sup> is -CH<sub>2</sub>-;

(17) R<sup>1</sup> is -OH, R<sup>2</sup> is -OH or =O, R<sup>3</sup> is -H, R<sup>4</sup> is -OR<sup>PR</sup>, -SR<sup>PR</sup>, -N(R<sup>PR</sup>)<sub>2</sub>, an ester, a thioester, a phosphoester, a monosaccharide, an oligosaccharide, a carbonate or a carbamate and R<sup>9</sup> is -CH<sub>2</sub>-;

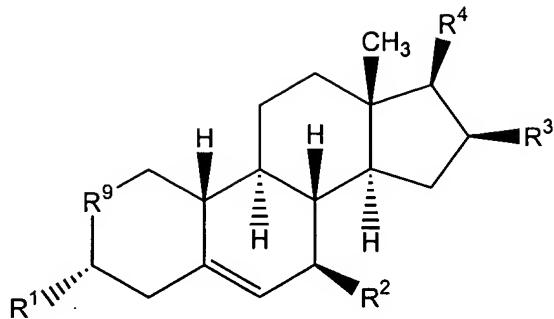
20 (18) any of (1) through (17) above wherein R<sup>9</sup> is -O- instead of -CH<sub>2</sub>-;  
or

(19) any of (1) through (17) above wherein R<sup>9</sup> is -NH- instead of -CH<sub>2</sub>-.

Claim 35 (new): The method of claim 32 wherein the compound has the structure



or



Claim 36 (new): The method of claim 35 wherein the subject has osteoporosis and the compound is 3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrostan-4-ene,  
5 3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrostan-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxyandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxyandrost-5-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-19-norandrostan-4-ene,  
3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxy-19-norandrostan-5-ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxyandrost-4-  
ene, 3 $\alpha$ ,16 $\alpha$ ,17 $\beta$ -trihydroxyandrost-5-ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxy-19-norandrostan-4-  
ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxy-19-norandrostan-5-ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxyandrost-4-  
10 ene, 3 $\alpha$ ,7 $\beta$ ,17 $\beta$ -trihydroxyandrost-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoro-19-  
norandrostan-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoro-19-norandrostan-5-ene, 3 $\alpha$ ,17 $\beta$ -  
dihydroxy-16 $\alpha$ -fluoroandrost-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -fluoroandrost-5-ene,  
3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromo-19-norandrostan-4-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -  
bromo-19-norandrostan-5-ene, 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromoandrost-4-ene or  
15 3 $\alpha$ ,17 $\beta$ -dihydroxy-16 $\alpha$ -bromoandrost-5-ene.

Claim 37 (new): The method of claim 36 wherein the compound is  
3 $\alpha$ ,17 $\beta$ -dihydroxy-19-norandrostan-4-ene.